

REMARKS

I. The Office Action

The Office withdrew the requirement for election of species between matrix metalloprotease-2 (MMP-2) and matrix metalloprotease-9 (MMP-9), but the requirement for restriction between Groups I-XXVI in the Office Action dated February 2, 2009, was made final. Claims 1-29, 37, and 40-62 have been withdrawn from further consideration. Claims 30-36, 38, and 39 are under examination insofar as the claims are directed to a method of generating hematopoietic stem cells suitable for transplantation.

Claims 30-36, 38, and 39 were rejected under 35 U.S.C. § 112, second paragraph, for assertedly being indefinite. Claims 30-36, 38, and 39 also were rejected under 35 U.S.C. § 102(b) for assertedly lacking novelty in view of Kollet et al., *Blood*, 97(10), 3283-91 (2001) (“the Kollet 2001 reference”), and Kollet et al., *Exp. Hematol.*, 28(6), 726-36 (2000) (“the Kollet 2000 reference”), as evidenced by Janowska-Wieczorek et al., *Blood*, 93(10), 3379-90 (1999) (“the Janowska-Wieczorek reference”). Reconsideration of these rejections is respectfully requested.

II. The Amendments to the Claims

Claims 30, 38, and 39 have been amended to recite that the matrix metalloprotease is an exogenous matrix metalloprotease, and that the method comprises isolating stem cells having increased CXCR4 levels compared to stem cells not exposed to the matrix metalloprotease or an active portion thereof. The amendments are supported by the specification at, e.g., page 12, lines 24-30, page 32, line 17, through page 33, line 29, and Example 4. Withdrawn claims 41, 43, and 60-62 have been amended to correct typographical errors. No new matter has been added by way of the amendments.

III. The Rejection Under 35 U.S.C. § 112, Second Paragraph, Should Be Withdrawn.

Claims 30-36, 38, and 39 were rejected under 35 U.S.C. § 112, second paragraph, because the term “predetermined threshold” assertedly renders the claims indefinite. Claim 30 has been amended to cancel the language cited by the Office and, instead, to recite that step (c) comprises isolating stem cells having increased CXCR4 levels

compared to stem cells not exposed to the matrix metalloprotease or an active portion thereof. One of ordinary skill in the art would understand the metes and bounds of claim 30 (and claims 31-36, 38, and 39 dependent thereon) and, therefore, the rejection under Section 112, second paragraph, should be withdrawn.

IV. The Rejection Under 35 U.S.C. § 102(b) Should Be Withdrawn.

The Office rejected claims 30-36, 38, and 39 under 35 U.S.C. § 102(b) for assertedly lacking novelty in view the Kollet 2001 reference and the Kollet 2000 reference, as evidenced by the Janowska-Wieczorek reference. This rejection is respectfully traversed for the reasons set forth below.

Claim 30 is directed to a method of generating stem cells suitable for transplantation. The method comprises (a) collecting stem cells; (b) exposing said stem cells to an exogenous matrix metalloprotease (MMP) or an active portion thereof; and (c) isolating stem cells having increased CXCR4 levels compared to stem cells not exposed to the MMP or an active portion thereof, to thereby generate stem cells suitable for transplantation.

Anticipation under § 102(b) can be found only when a reference discloses exactly what is claimed. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 780 (Fed. Cir. 1985). Here, the references cited by the Office fail to teach or suggest each and every feature of the pending claims. The Kollet references purportedly disclose isolating CD34⁺ stem cells from cord blood, purifying a subpopulation of CD34⁺CD38⁻ cells, and incubating stem cells with stem cell factor (SCF). The references do not explicitly disclose exposing stem cells to an MMP or active portion thereof, as recited in step (b). The Office cited the Janowska-Wieczorek reference as disclosing that CD34⁺ cells *inherently* express MMP-2 and MMP-9 in the presence and, in some cases, in the absence of SCF. (Office Action, pages 8 and 11-12.) Thus, according to the Office, the Kollet references' disclosures of exposing stem cells to SCF inherently disclose step (b) of the claimed method because SCF *necessarily* induces MMP production and, as a consequence, stem cells are exposed to an MMP. In contrast, the claimed method comprises exposing collected stem cells to an *exogenous* MMP or an active portion thereof. The cited references do not teach (or even suggest) contacting stem cells with exogenous MMP. Moreover, the cited references do not disclose or suggest the isolation

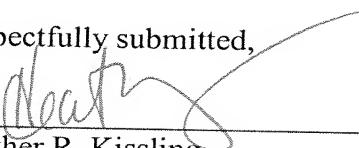
of stem cells having increased CXCR4 levels relative to stem cells not exposed to the MMP. Thus, the references do not disclose each element of any one of the rejected claims and, for that reason, cannot anticipate the pending claims under Section 102(b). Accordingly, the rejection should be withdrawn.

V. Conclusion

In view of the above amendments and remarks, Applicants believe that the pending application is in condition for allowance. The Office is invited to contact the undersigned attorney by telephone if there are issues or questions that might be efficiently resolved in that manner.

Dated: October 12, 2009

Respectfully submitted,

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